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Proposed Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12 VAC 5 - 421
Regulation title	Food Regulations
Action title	Amendment
Document preparation date	June 8, 2006

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

The Food Regulations establish minimum sanitary standards for operating restaurants. These standards include standards for the safe and sanitary maintenance, storage, operation, and use of, the safe preparation, handling, protection, and preservation of food, including necessary refrigeration or heating methods, procedures for vector and pest control, requirements for appropriate lighting and ventilation not otherwise provided for in the Uniform Statewide Building Code, requirements for an approved water supply and sewage disposal system, personal hygiene standards for employees, particularly those engaged in food handling, and the appropriate use of precautions to prevent the transmission of communicable diseases. The regulations also inform potential restaurant owners or operators how to obtain a permit to operate a restaurant from the Department. The regulations are being amended to be consistent with the 2003 supplement to the 2001 FDA Food Code. The current Food Regulations are based on the FDA 1999 FDA Food Code. These changes are also being proposed concurrently with the Virginia Department of Agriculture and Consumer Services' (VDACS) adoption of the 2003 supplement to the 2001 FDA Food Code. Pursuant to § 35.1-14 C

and E of the *Code of Virginia*, this action is exempt from portions of the Administrative Process Act provided VDACS adopts the same version and both agency's regulations have the same effective date. Both agencies are working to that end. However, since VDH's current Food Regulations are based on the FDA 1999 Food Code, VDH is simply amending our existing regulations. VDACS, on the other hand, is adopting the FDA Food Code for the first time.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

The amendment to these regulations is exempt from the requirements of the APA pursuant to § 35.1-14.E of the Code of Virginia. The Board still has to comply with subsections F, H, and I of § 2.2-4007 of the Code of Virginia. This form is being used to satisfy those requirements. The regulations are authorized and mandated by Sections 35.1-11 and 35.1-14 of the Code of Virginia. The code requires the regulations to provide minimum standards for the following: (i) a procedure for obtaining a license; (ii) the safe and sanitary maintenance, storage, operation, and use of equipment; (iii) the sanitary maintenance and use of a restaurant's physical plant; (iv) the safe preparation, handling, protection, and preservation of food, including necessary refrigeration or heating methods; (v) procedures for vector and pest control; (vi) requirements for toilet and cleansing facilities for employees and customers; (vii) requirements for appropriate lighting and ventilation not otherwise provided for in the Uniform Statewide Building Code; (viii) requirements for an approved water supply and sewage disposal system; (ix) personal hygiene standards for employees, particularly those engaged in food handling; and (x) the appropriate use of precautions to prevent the transmission of communicable diseases.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the regulations is to ensure that the dining public is protected by establishing minimum sanitary standards for restaurants. The regulations provided minimum standards for the source of foods in restaurants, the safe handling, storage, preparation and serving of food, personnel hygiene of the employees, precautions to prevent the transmission of diseases communicable through food, and the general sanitation of the facility. When followed, these minimum standards will protect the public's health, safety and welfare.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)

The proposed regulations will amend the current Food Regulations so they will be consistent with the 2003 Supplement to the 2001 FDA Food Code. The FDA Food Code is the reviewed every other year at the Conference for Food Protection. The conference is attended by regulators from all 50 states and Puerto Rico, academia from across the nation, food processors, food distributors, food scientists, food service establishments and other interested parties. Recommendations resulting from the conference are forwarded to FDA for consideration in the next version of the Food Code, which is modified every four years with a supplement, if necessary, issued two years after the Food Code's issuance. The FDA Food Code represents the most current standards based on current food science and technology. Most of the changes being proposed in this amendment process are to increase clarity of the regulations but there will be some changes the current standards that will reflect current food science and safety knowledge. VDH's current Food Regulations became effective on March 1, 2002 and are based on the 1999 FDA Food Code. This is the first update since their adoption. The current regulations were reviewed and compared to the 2003 supplement to the 2001 FDA Food Code by a committee comprised of VDH staff, academia, VDACS and members of the Virginia Hospitality and Travel Association (the parent association over the Virginia Restaurant Association). The committee was in agreement the regulations should be updated to the 2003 supplement. The two major changes to the regulations are the addition of a consumer advisory requirement and the reduction of the hot holding temperature for potentially hazardous foods from 140°F to 135°F. The consumer advisory requirement will require restaurants to advise customers, through either statements on the menu or signs in the establishments, of the risks involved in eating raw or partially cooked foods of animal origin. The reduction in the hot holding temperature is supported by food science data indicating pathogenic bacterial associated with various foodborne illnesses do not multiply rapidly at temperatures of 135°F or higher.

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
- 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
- 3) other pertinent matters of interest to the regulated community, government officials, and the public.*

If the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

The primary advantage of the regulations to the public is that they establish modern science-based standards that has broad support in the food service and food regulatory communities. The revisions will also make the regulations more understandable. The primary advantage to the agency is the regulations will be based on current food science. The primary advantage to the

regulated community, particularly chains that operate in other states, will be better consistency between states as more adopt the FDA Food Code. There will be no disadvantages to the public or the Commonwealth with the adoption of these regulations.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

<p>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures</p>	<p>Little or no additional cost to implement. Restaurants are already under inspection by VDH. The proposed changes do not include any change in the inspection process.</p>
<p>Projected cost of the regulation on localities</p>	<p>None, for the same reasons as above.</p>
<p>Description of the individuals, businesses or other entities likely to be affected by the regulation</p>	<p>Restaurants operating in the Commonwealth of Virginia.</p>
<p>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>Currently approximately 25,000 restaurants in the Commonwealth. Based on employing 500 or fewer employees, estimated 95 to 100% of the total number of restaurants will fall into the small business category.</p>
<p>All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.</p>	<p>The regulations will not place any additional reporting or recordkeeping requirements upon the restaurants beyond what they already have. There may be some small costs to some restaurants that will have to either revise their menus or post signs to advise consumers of the hazards of consuming raw or partially cooked animal products. Most national chain restaurants already have statements such as these on their menus. Restaurants will see a benefit if they consistently comply with the provisions of the regulations. Consistent compliance will significantly reduce the chance of the facility being the source of a foodborne outbreak. as they will lose less food to impounm</p>

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.

The existing *Food Regulations* were reviewed by a committee composed of department personnel, academia, VDACS staff, members of the Virginia Hospitality and Travel Association (i.e., restaurant association). The current regulations were compared to the *2001 FDA Food Code* and the 2003 supplement thereto. The review concluded the regulation to be essential; however, the committee did identify sections that may need clarification. Such sections were amended. The regulations were also reviewed with VDACS to ensure they were consistent with the substantive requirements of their regulations.

Public comment

Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.

Commenter	Comment	Agency response

No public comment was received during the NOIRA comment period.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

These regulations should not have any impact on the institution of the family and family stability.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if	Current requirement	Proposed change and rationale

	applicable		

Description of Changes to Food Regulations

Section	Discussion
12 VAC 5-421-10	Some new definitions that reflect changes in the regulations. No really substantive change that will have an economic impact.
12 VAC 5-421-90	Wording change – no substantive change.
12 VAC 5-421-100	Wording change – no substantive change
12 VAC 5-421-120	Changed identification of Escherichia coli.
12 VAC 5-421-140	Wording and format change. Added reference to prosthetic devices.
12 VAC 5-421-160	Wording change in subsection 8.
12 VAC 5-421-170	Addition of reference to automatic handwashing facilities.
12 VAC 5-421-180	Simplified language.
12 VAC 5-421-190	Stricter prohibition on fingernail polish and artificial nails.
12 VAC 5-421-200	Change “may not” to “shall not”
12 VAC 5-421-230	Change “may not” to “shall not”
12 VAC 5-421-270	Clarification of whole-muscle, intact beef requirements. Additional language regarding untreated shell eggs.
12 VAC 5-421-295	New addition concerning pre-packaged juice. Should not affect restaurants. Added section to be consistent with VDACS regs.
12 VAC 5-421-300	Change “may not” to “shall not”
12 VAC 5-421-330	Updated references to CFRs.

12 VAC 5-421-340	Added requirement for refrigeration of shell eggs. Amended language to reflect 135° F hot holding temperature.
12 VAC 5-421-350	Updated reference to CFR and changed “may not” to “shall not”
12 VAC 5-421-430	Wording change for clarity.
12 VAC 5-421-440	Wording change for clarity.
12 VAC 5-421-450	More stringent bare-hand contact prohibition.
12 VAC 5-421-460	New addition – prohibits multiple use of tasting utensil.
12 VAC 5-421-500	Subsection B change “may not” to “shall not”
12 VAC 5-421-530	Change “may not” to “shall not”
12 VAC 5-421-550	Changed 140° to 135°F
12 VAC 5-421-560	Changed “may not” to “shall not.”
12 VAC 5-421-570	Added provision for working containers of sanitizing solutions.
12 VAC 5-421-580	Changed “may not” to “shall not” in subsection D
12 VAC 5-421-620	Changed “may not” to “shall not.”
12 VAC 5-421-670	Wording change for clarity – added exemption for raw, frozen, shell-on shrimp or lobster.
12 VAC 5-421-700	Changes to table to offer more alternative cooking temps and to correct an error. Added language in subsection D regarding consumer advisory, which will now be required.
12 VAC 5-421-720	Changed final cook temperature for cooked fruits and vegetables for hot holding from 140°F to 135°F.
12 VAC 5-421-760	Changed reheating temp for certain foods from 140°F to 135°F. Change “may not” to “shall not”
12 VAC 5-421-765	New addition regarding packaging of juice. Should not affect any restaurants.
12 VAC 5-421-780	Changed cross-reference
12 VAC 5-421-790	Changed wording for clarity.

12 VAC 5-421-800	Changed 140°F to 135°F and reworded for clarity.
12 VAC 5-421-820	Changed 140°F to 135°F and reworded. Added requirement to refrigerate shell eggs.
12 VAC 5-421-830	Edited for clarity.
12 VAC 5-421-840	Edited for clarity.
12 VAC 5-421-850	Subsection B, changed “may not” to “shall not.”
12 VAC 5-421-860	Edited for clarity.
12 VAC 5-421-870	Updated CFR references.
12 VAC 5-421-880	Added requirements for standards of identity. Should not affect restaurants. Was added so be consistent with VDACS regs.
12 VAC 5-421-890	Added requirements for honestly presented. Should not affect restaurants. Was added so be consistent with VDACS regs.
12 VAC 5-421-900	Added requirements for labeling packages of food packaged in a food establishment. Should not affect restaurants. Was added so be consistent with VDACS regs.
12 VAC 5-421-910	Added requirements regarding other forms of information.
12 VAC 5-421-930	Added requirements for disclosure and reminders regarding consuming raw or undercooked animal products.
12 VAC 5-421-950	Reworded, particularly requirements for juice.
12 VAC 5-421-970	Change “may not” to “shall not”
12 VAC 5-421-990	Added requirements for exemption to copper use in making apple butter and molasses. Reworded and changed “may not” to “shall not.”
12 VAC 5-421-1010 through 1030	Change “may not” to “shall not” in each section.
12 VAC 5-421-1070	Change “may not” to “shall not”
12 VAC 5-421-1090	Change “may not” to “shall not.”
12 VAC 5-421-1120	Change “may not” to “shall not.”

12 VAC 5-421-1200	Moved exemption for certain B&Bs to 12 VAC 5-421-4035
12 VAC 5-421-1260	Change “may not” to “shall not.”
12 VAC 5-421-1270	Change “may not” to “shall not.”
12 VAC 5-421-1300	Change “may not” to “shall not.”
12 VAC 5-421-1310	Change “may not” to “shall not” and changed 140° to 135°F.
12 VAC 5-421-1320	Rewording – no substantive change. Moved B&B exemption to 12 VAC 5-421-4035
12 VAC 5-421-1330	Moved B&B exemption to 12 VAC 5-421-4035
12 VAC 5-421-1340	Moved B&B exemption to 12 VAC 5-421-4035
12 VAC 5-421-1350	Moved B&B exemption to 12 VAC 5-421-4035
12 VAC 5-421-1360	Moved B&B exemption to 12 VAC 5-421-4035
12 VAC 5-421-1370	Reworded to identify date when warewashing machines must meet requirement. No change in date, just specified specific date rather than “Within five years of...adoption...” Moved B&B exemption to 12 VAC 5-421-4035
12 VAC 5-421-1460	Reworded for clarity, changed “shall not” to “may not”, and moved B&B exemption to 12 VAC 5-421-4035
12 VAC 5-421-1510	Clarifies that a temperature measuring device suitable for measuring temperature of thin masses must be provided.
12 VAC 5-421-1520	Moved B&B exemption to 12 VAC 5-421-4035
12 VAC 5-421-1530	Moved B&B exemption to 12 VAC 5-421-4035
12 VAC 5-421-1540	Changed “may not” to “shall not.”.
12 VAC 5-421-1620	Changed “may not” to “shall not.”
12 VAC 5-421-1640	Moved B&B exemption to 12 VAC 5-421-4035
12 VAC 5-421-1660	Changed “may not” to “shall not” and moved B&B exemption to 12 VAC 5-421-4035

12 VAC 5-421-1670	Moved B&B exemption to 12 VAC 5-421-4035
12 VAC 5-421-1680	Changed “may not” to “shall not.” Moved B&B exemption to 12 VAC 5-421-4035.
12 VAC 5-421-1690	Changed “may not” to “shall not.” Moved B&B exemption to 12 VAC 5-421-4035
12 VAC 5-421-1700	Moved B&B exemption to 12 VAC 5-421-4035
12 VAC 5-421-1710	Moved B&B exemption to 12 VAC 5-421-4035
12 VAC 5-421-1720	Moved B&B exemption to 12 VAC 5-421-4035
12 VAC 5-421-1730	Removed reference to B&B in subsection C.
12 VAC 5-421-1750	Changed “may not” to “shall not.”
12 VAC 5-421-1760	Changed “may not” to “shall not.”
12 VAC 5-421-1780	Changed 140° to 135°F.
12 VAC 5-421-1810	Changed “may not” to “shall not”
12 VAC 5-421-1820	Removed word “scupper.”
12 VAC 5-421-1880	Moved B&B exemption to 12 VAC 5-421-4035
12 VAC 5-421-1890	Moved B&B exemption to 12 VAC 5-421-4035
12 VAC 5-421-1960	Changed “may not” to “shall not.”
12 VAC 5-421-2010	Changed “may not” to “shall not.”
12 VAC 5-421-2080	Rewording to clarify what has been done by policy for years.
12 VAC 5-421-2190	Changed 110 to 100 and changed “may not” to “shall not.”
12 VAC 5-421-2270	New Addition . Requires double check valve if air gap not provided upstream of a carbonating device and downstream from any copper. Consistent with plumbing practice for years.
12 VAC 5-421-2310	Changed “may not” to “shall not.”
12 VAC 5-421-2320	Changed “may not” to “shall not.”

12 VAC 5-421-2520	Changed “may not” to “shall not.”
12 VAC 5-421-2630	Changed “may not” to “shall not.”
12 VAC 5-421-2680	Changed “may not” to “shall not.”
12 VAC 5-421-2790	Moved B&B exemption to 12 VAC 5-421-4035
12 VAC 5-421-2810	Moved B&B exemption to 12 VAC 5-421-4035
12 VAC 5-421-2820	Moved B&B exemption to 12 VAC 5-421-4035
12 VAC 5-421-2840	Changed “may not” to “shall not.” Moved B&B exemption to 12 VAC 5-421-4035
12 VAC 5-421-2850	Moved B&B exemption to 12 VAC 5-421-4035
12 VAC 5-421-2870	Moved B&B exemption to 12 VAC 5-421-4035
12 VAC 5-421-2880	Changed “may not” to “shall not.”
12 VAC 5-421-2930	Rewording for clarity – removed reference to temporary food establishment. Clarifies air curtains are for controlling flying insects.
12 VAC 5-421-2990	Changed “may not” to “shall not”
12 VAC 5-421-3040	Changed “may not” to “shall not”
12 VAC 5-421-3120	Moved B&B exemption to 12 VAC 5-421-4035
12 VAC 5-421-3200	Changed “may not” to “shall not”
12 VAC 5-421-3210	Changed “may not” to “shall not”
12 VAC 5-421-3230	Changed “may not” to “shall not”
12 VAC 5-421-3310	Changed “may not” to “shall not” and changed term group residences to more meaningful descriptions.
12 VAC 5-421-3370	Changed “may not” to “shall not”
12 VAC 5-421-3450	Changed “may not” to “shall not”
12 VAC 5-421-3510	Corrected cross-references in subsection B.

12 VAC 5-421-3620	Removed a cross reference.
12 VAC 5-421-3660	Added subsection E, specifying that permits expire annually – has been practice for years.
12 VAC 5-421-3750	Rewording - no substantive change.
12 VAC 5-421-3760	Changed “may not” to “shall not”
12 VAC 5-421-3815	New addition. Requires EHS who inspect establishments or conduct plan review to demonstrate competency.
12 VAC 5-421-4035	New addition. Moved all references that were scattered throughout regs exempting certain facilities from specific parts of the regulations (primarily B&Bs) from their original sections to one section for ease in finding them.
12 VAC 5-421-4050	Reworded for clarity.
12 VAC 5-421-4070	Updated reference to Escherichia coli O157:H7 to Shiga toxin-producing Escherichia coli.